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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/720,382	03/07/2001	Reynolds Paul Ross	681353342002	2369

7590 03/13/2002

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EXAMINER
HENDRICKS, KEITH D

ART UNIT	PAPER NUMBER
1761	

DATE MAILED: 03/13/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/720,382	Applicant(s) ROSS ET AL.
	Examiner Keith Hendricks	Art Unit 1761

-- Th MAILING DATE of this communication appears on the cover sheet with the correspond nc address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-15* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-15* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Specification

This application does not contain an abstract of the disclosure as required by 37 CFR 1.72(b). An abstract on a separate sheet is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-15 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

NOTE: *This application claims priority to a foreign document. Applicants' representative is* strongly *encouraged to review the application, especially the claims, to comply with accepted U.S. Patent structure and language.* The claims *are generally narrative and indefinite, failing to conform with current U.S. practice, and* are replete with grammatical and idiomatic errors. *The rejections under 35 USC 112 2nd paragraph below are an attempt to call attention to these occurrences, yet may not be comprehensive.*

In claim 1:

- Part (c), it is unclear what steps are to be performed if the pH already falls within the recited range of 6.3 to 6.7, thus lacking the need to be "adjusted".

To this point, see also claim 5.

- Further with regard to part (c) of claim 1, the phrase "to pH 6.3 to 6.7" is unclear as to whether this is a range (i.e. "to a pH ranging from 6.3 to 6.7", is suggested), or two particular separate points along a steady gradient, to which the fermentate is to be "adjusted".
- In part (d), it is unclear as to how the step of "inactivating the bacterial fermentate" is to be carried out. Further, it is unclear as to what portion(s) and activity, or activities, the fermentate itself possesses, which would need to be inactivated.

In claim 2:

- The phrasing of the multitude of choices of media is not in compliance with accepted U.S. Patent language. The use of the connecting phrases of "*selected from* milk *or* dairy-based... powders *or* synthetic laboratory-type... *and* TY broth", renders the claim indefinite, as it is unclear as to what limitations are encompassed by the claim.

It is unclear if the term "including", at line 2, also refers to the synthetic laboratory-type media, as well as every recited type in between, or simply those up to that point.

- The phrase "selected from milk or dairy-based powders including demineralized whey powder...", is confusing, as it is unclear if this refers to

  (1) milk-based or dairy-based powders, or

  (2) (a) milk, or (b) dairy-based powders.

  It is noted that option (1) is redundant and indefinite, presenting an unclear distinction between the two.
- The phrase "such as" renders the claim indefinite because it is unclear whether the limitations following the phrase are part of the claimed invention. See MPEP § 2173.05(d).
- It is unclear as to how the powders recited may be used as the medium to be inoculated with the bacteria, whereby a presumably liquid fermentate is evaporated from the culture medium (as in claim 1, step (e)). It is believed that these should be reconstituted powders, but this is unclear from the claims. Support from the specification is required if amended as such.

In claim 3:

- The phrase "the concentrate" lacks a clear and specific antecedent basis within the claim(s). No particular component is previously referred to as "the concentrate."
- Given that step (e) of claim 1 would appear to produce a concentrate, it is unclear if the method step of claim 3:
  (1) represents the further method limitation (i.e. a more precise explanation) of the process of step (e) of claim 1, in order to produce a concentrate, or
  (2) should actually be a separate and subsequent step (f) with regard to claim 1, to further process any concentrate already produced by step (e).

In both the claims and specification, terms such as "pasteurisation", "crystallised", etc. should be spelled in accordance with accepted U.S. language, as this is a U.S. filed application. For example, "crystallised" should be "crystallized".

Claim 7 is suggested to be amended as follows:

- delete the term "if", as a potential scenario does not clearly and distinctly point out the claimed invention.
- insert the term "and" between "pasteurized, " and "it is". This clearly points out that the option of pasteurization is selected from claim 6, *and* then sets forth the conditions.

Similar to claim 3, it is unclear if the step(s) of claim 8:

(1) represent the further method limitation (i.e. a more precise explanation) of the process of step (d) of claim 1, in order to produce a concentrate, or
(2) should actually be a separate and subsequent step between (d) and (e) with regard to claim 1, as a preliminary process of evaporation before a second evaporation of step (e).

In claim 8, it is believed that the recited temperature of 6° C, should in fact be 60° C. This is supported by the specification at page 7, line 22. However, if this change is accurate, then page 3 of the specification should also be amended. It is unclear as to which temperature is accurate; however, it is believed that both would not yield the claimed 40% solids upon evaporation under otherwise the same conditions, and thus one must be incorrect and amended.

In claim 9, the term "the crystallised concentrate" lacks a clear antecedent basis previously in the claim(s).

Further, in claim 9, it is unclear if the spray-drying results in producing a crystallized concentrate, or if a crystallized concentrate produced by some unspecified process is subsequently further spray-dried.

Claim 10 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite, in that it fails to point out what is included or excluded by the claim language. This claim is an omnibus type claim.

In claim 11, the phrase "whenever produced by a process as claimed in any of claims 1 to 10", does not further limit and sufficiently describe the claimed product by accepted U.S. practice.

Claims 11-15 are indefinite, as they contain the limitation of a "spray-dried lacticin powder", and depend from any of claims 1-8, none of which provide steps for such a spray-dried product.

Regarding claims 12 and 15, the phrases "preferably" and "more preferably" render the claims indefinite because it is unclear whether the limitations following the phrases are part of the claimed invention. See MPEP § 2173.05(d).

Claim 13 is indefinite, as it fails to further define over the product of claim 11 or 12, as no further components are recited that would serve to distinguish the "food product comprising a spray-dried lacticin 3147" in claim 13, over the "spray-dried lacticin 3147" of claims 11-12.

Regarding claim 14, the phrase "such as" renders the claim indefinite because it is unclear whether the limitations following the phrases are part of the claimed invention. See MPEP § 2173.05(d).

Claim 14 is indefinite, as the terms "dessert" and "custard" are not mutually exclusive options as claim limitations. The metes and bounds of the claimed invention are unclear.

Claim 14 is indefinite, as it refers to "a food product as claimed in claim 12". Claim 12 does not recite a food product.

The term "increased" in claim 15 is a relative term which renders the claim indefinite. The term is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention.

Claims 4-11, 13 and 15 are objected to under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim should refer to other claims in the alternative only, *and/or* because a multiple dependent claim cannot depend from another multiple dependent claim. See MPEP § 608.01(n).

In addition, claim 13 improperly depends from two statutory classes of invention, both a product and a process.

Claim 15 improperly refers to two different claims, requiring the limitations of both at the same time (by the term "and").

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 11-13 are rejected under 35 U.S.C. 102(b) as being anticipated by McAuliffe et al., of record, published February 1999 (vol. 2).

McAuliffe et al. teach a concentrated lacticin 3147, which was dialyzed and precipitated from culture media supernatant. As lacticin 3147 in any form, spray-dried or otherwise, is still the same compound, and is that which is claimed, the instant invention is anticipated by the reference. "The preparation of a known product in a specific physical form does not ender novel said known product" (cited from PCT form 409, as provided from applicants' International application).

Claims 11-15 are rejected under 35 U.S.C. 102(b) as being anticipated by Ryan et al. (WO 96/32482, a copy of which was provided to applicant with the International Search Report).

Ryan et al. disclose the concentration and freeze-drying of lacticin 3147. See pages 13-14. The use of lacticin 3147 in various food products is disclosed, including in vegetable and meat preparations, and canned foods, which are traditionally subjected to increased pressure over that of atmospheric pressure. See claim 9 of the reference, for example. As lacticin 3147 in any form, spray-dried, freeze-dried or otherwise, is still the same compound, and is that which is claimed, the instant invention is anticipated by the reference. "The preparation of a known product in a specific physical form does not ender novel said known product" (cited from PCT form 409, as provided from applicants' International application). Further, there does not appear to be any difference between the freeze-dried product of the reference, and the instantly-claimed spray-dried product.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ryan et al. (WO 96/32482), in view of DE 2616390 (English abstract provided).

Ryan et al. WO '482 is taken as cited above. Further, the reference discloses the growth of *Lactobacillus lactis* overnight on LM17 (pg. 12), TY (pg. 13), and whole milk (pg. 7) fermentation broths, to produce lacticin 3147. The media was "supplemented with 0.5% glucose or lactose" (pg. 7). The cells were cultured at 30° C (mid-pg. 12, top pg. 13). At line 30 of page 5, it is stated that "since the biological activity of the bacteriocin of the present invention is similar to that of nisin, it could be used for similar applications." At page 2, Ryan et al. states that the bacteriocin nisin is also produced by strains of *Lactobacillus lactis*, as well as other bacteria.

DE 2616390 disclose the production of a spray-dried "nisin-enriched milk powder". Skim milk is inoculated with a nisin-producing bacterial culture, and fermented for 18 hours at a pH between 6.0 and 6.8, at 28-33 degrees C. The resultant media is cooled to 10-14 degrees C after fermentation, using a heat exchanger, concentrated to 14-25% solids, spray-dried at 87-97 degrees, and cooled as it leaves the drier.

Thus, it would have been obvious to one of ordinary skill in the art to have produced lacticin 3147 in spray-dried powder form. Ryan et al. specifically provide the connection between lacticin 3147 and the known bacteriocin, nisin. DE `390 demonstrates known steps in the art for the culturing and production of bacteriocins powders. The abstract of DE `390 does not teach the inactivation of the bacterial culture; however, as it teaches that this may be used in food products, it follows that inactivation of the bacteria prior to such drying and use, would have been an obvious safety step, well-known in the art. The particular parameters instantly claimed, such as the use of lactose to seed crystals, and heat-inactivation of bacteria, were well-known and commonly practiced in the art, and would not have involved an inventive step for one of ordinary skill, given the specific teachings of the references and the common state of the art at the time the invention was made. The variation of temperature and solids percentage, would have been easily provided by one of ordinary skill in the art, based upon the properties of the culture media, the stability of the lacticin 3147, the type of dryer utilized, and the state of the art at the time the invention was made.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Keith Hendricks whose telephone number is (703) 308-2959. The examiner can normally be reached on M-F (8:30am-6pm); First Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Milton Cano can be reached on (703) 308-3959. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 305-3602 for regular communications and (703) 872-9565 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0661.

KEITH HENDRICKS
PRIMARY EXAMINER

March 7, 2002